The proposals of the Advisory Committee on Administrative Reform:

Lessons Learned from drug-induced hepatitis

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1 What's "the Advisory Committee on Administrative Reform : Lessons Learned from Drug-Induced Hepatitis"?

"The Advisory Committee on Administrative Reform : Lessons Learned from Drug-Induced Hepatitis "was established in May 2008, by the Ministry of Health, Labor and Welfare (MHLW), based on "The fundimental agreement" drawn up between national plaintiffs groups, their lawyers' groups and the MHLW, concerning the drug-induced hepatitis C litigation.

The committee's purpose is to verify the Drug-Induced Hepatitis Scandal and make practical proposals on administrative reform to prevent a recurrence of drug-induced disasters.

In April 2010, after two years' deliberations, the committee released a report entitled "Proposals for Administrative Reform in Preventing a Recurrence of Drug-induced Disasters" (132 pages).

2 Historical significance

Japan has witnessed the recurrence of drug-induced disasters such as Thalidomide, SMON (subacute myelo-optic-neuropathy), dura mater infected with Creutzfeldt-Jakob Disease, HIV-tainted blood products, and class actions have been filed repeatedly by victims, not only for compensation, but also to clarify the government's responsibility, establish permanent measures for victims, find the true facts, and develop preventive measures.

In response to each litigation, regulatory systems have been forced to change little by little.

However, this is the first time that the MHLW has established an advisory committee to learn from drug-induced disasters and make practical proposals for administrative reform in order to prevent further disasters.

The committee is a new and significant development of "Form-Policy-Function" of pharmaceutical class action. .

3 Outline of the proposals for administrative reform

The report consists of two parts. Part one is about the verification of drug-induced hepatitis, and Part two covers proposals for administrative reform.

In the administrative reform part, the report presents the following fundamental view related to the cause of drug induced disasters: "The

problem exists in decision making. True information has not reached doctors and patients, even though it has reached drug companies and the MHLW."

The report emphasizes that "a precautionary principle" is essential, and proposes drastic reform measures for the entire system, including the way of Pharmaceutical and Food Safety Bureau, the Pharmaceuticals and Medical Devices Agency(PMDA), human resource development, and education.

Regarding clinical trials, the report proposes as follows:Clinical trial registrations be made compulsory. Items for registration and disclosure should be broad. Examinees' rights should be legally defined. A unified legal system through clinical trials and other clinical research should be also be established.

The fundamental view of the above proposal is that transparency is essential, as is the establishment of a foundation independent from the influence of drug companies.

Regarding approval reviews, the report has proposed the following, based on the view that both rapid approval and drug safety are important: The qualifications and quality of PMDA reviewers should be enhanced. Conditions of approval and evaluations of performances and conditions should be checked thoroughly. Transparency, such as disclosure of the review process before approval, should also be improved. The MHLW's responsibility for the package inserts included with the drugs should be made clear as well.

Regarding post-marketing safety measures, the report suggests that approval reviews and post-marketing measures should be harmonized so that anything found during the approval process can be further shared in the post-marketing safety system. Pharmacoepidemiology should be included more in post-marking safety measures. A new receipt database system should be established so that the number of people using the drug users make clear.

A regulatory system for unapproved drugs and devices should also be established. Risk communication should be improved, as should the regulation system on package inserts, and a reporting system to accept ADR information from patients is also necessary.

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The report has proposed that doctors and patients become more familiar with a relief system for suffers of adverse drug reactions, and that the range of objects for relief, including anti-cancer drugs, be broadened.

4 A third party organization to inspect and evaluate drug regulations

More noteworthy is a proposal by the committee to set up a third party organization to inspect and evaluate drug regulations.

It will first launch as a standing counsel to watch and evaluate the entire drug regulation process, and recommend that the MHLW take particular action, in order to prevent drug-induced disasters. The counsel consists of ten people who are drug-induced victims and specialists in various fields and will be independent from the MHLW. .

For ten years, the Japan Federation of Bar Associations and Medwatcher Japan have been demanding the establishment of such an organization.

5 Future Issues

Even though the report is imperfect due to the limited deliberation period, it is essential to work towards achieving them.

We need to take action!